

**2002 REVIEW OF STRATEGIC HIV/AIDS,
HEPATITIS C AND INDIGENOUS SEXUAL
HEALTH RESEARCH AND THE NATIONAL
AND COLLABORATING CENTRES IN HIV
RESEARCH**

**Dr Linda Selvey
Associate Professor Ian Anderson
Professor John Mathews
Professor Sally Redman
Dr Stuart Shapiro**

4.1 SUMMARY AND RECOMMENDATIONS

4.1.1 Summary

This report examines the central elements of Australia's research efforts in the areas of HIV/AIDS, hepatitis C and the sexual health of Indigenous Australians. It is part of the broader review of Australia's public health response in these areas, which also includes reviews of the fourth National HIV/AIDS Strategy and the first National Hepatitis C Strategy.

The report contributes to the overall review by drawing together the principal findings of the quinquennial reviews of the National Centres in HIV Research, examining the historical context and contemporary requirements for research and recommending directions for future action.

Although some of the report's recommendations call for changes to existing arrangements, this should be considered against the background of Australia's world-class record of achievement in HIV/AIDS research. In terms of quality and the capacity of research to inform policy and practice, many aspects of Australian research in HIV/AIDS continue to be at the forefront internationally. The components of the research effort—principally the National Centres in HIV Research and their collaborating centres and partners—have consolidated their positions as core assets in Australia's public health response to HIV/AIDS. They have done this not only by conducting high-quality research but also by engaging the affected communities in setting research priorities and research dissemination, actively working to put research results into practice, and participating in policy development. These aspects of the National Centres' work need to be preserved. Cures and vaccines for HIV/AIDS, hepatitis C and STIs continue to elude us, but continued investment in a dedicated research program is essential to effective prevention, education, treatment and care.

The changing nature of the HIV/AIDS and hepatitis C epidemics and changing patterns of STIs, along with the evolution of health sector research funding and management do, however, present considerable challenges to future research efforts in these areas.

In particular, there is now a need to clarify the distinction between the various types of research and the most suitable support structures for each type. One facet of this concerns the positioning of investigator-initiated basic research within competitive grant programs (such as those administered by the NHMRC) and the positioning of core-funded research to optimise the development of health policy and programs. In addition, there is a pressing need to consider the position of hepatitis C research—in particular, funding levels and the involvement of research funding bodies such as the NHMRC. Similarly, it is also timely to consider the best way of funding and structuring research into Indigenous Australians' sexual health.

As Australian research in this area has evolved, so have the needs of the communities, individuals and organisations who rely on that research to provide an intellectual and informational base for their work. New ways of developing, communicating and assessing research priorities should now be forged. This report examines how all interested parties might be better served by improved processes for priority setting. The processes should seek to secure the best health outcomes whilst at the same time respecting the roles and responsibilities of all who have an interest in this research.

Having regard to the challenges of the HIV and hepatitis C epidemics, both in Australia and regionally, this report also highlights the importance of developing new ways of engaging with governments and with organisations responsible for HIV and hepatitis C policy and programs; this includes the states and territories and governments in the Asia-Pacific region.

As well as suggesting new ways of creating links into and out of research, the report offers a number of recommendations for maximising the relative strengths of the various components of the research response to the epidemics. It calls for funding bodies and host institutions to carefully consider the value of the assets represented by the National Centres in HIV Research and to structure future funding and support in such a way as to increase the value of those assets. This may involve further expanding the involvement of funding bodies such as the NHMRC and the Australian Research Council. It will, however, be necessary to retain the most successful and valuable features of Australia's highly regarded HIV/AIDS, hepatitis C and Indigenous sexual health research efforts, in order to ensure the research's continuing relevance and effectiveness.

4.1.2 Recommendations

The Strategy Research Review Team recommends as follows:

89. That the outgoing Director of the National Centre in HIV Virology Research be congratulated for the Centre's excellent work in carrying out important, internationally recognised research that is of very high quality and significance.
90. That the National Centre in HIV Virology Research, under the leadership of a Director, develop a strategic plan for the duration of its current funding cycle. This plan should guide the Centre's progress towards obtaining competitive funding; it should also include the important core research work (research that is highly strategic but may not necessarily be innovative). The strategic planning process should involve all stakeholders, including the HIV/AIDS advisory structure and the Department of Health and Ageing.
91. That scientists in the National Centre in HIV Virology Research review areas of commonality between the hepatitis C and human immunodeficiency viruses and their immunovirology and strengthen links with virologists working on hepatitis C in Australia and elsewhere. Where appropriate, funding could be sought for this research through the competitive grant processes.
92. That the National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society be congratulated for their high-quality, internationally recognised work in HIV social research.
93. That—where it is possible, feasible and appropriate—the National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society engage with National Centres on Drug Research when doing work relating to injecting drug users.
94. That the Director and Deputy Director of the National Centre in HIV Epidemiology and Clinical Research be congratulated for their outstanding achievements in HIV epidemiology, surveillance and clinical research.

95. That block funding for the National Centre in HIV Virology Research cease at the end of December 2004.
96. That a process be developed and funds be identified for purchasing 'core research' in HIV virology and immunovirology.
97. That a process be developed and funds be identified for purchasing a networking and communication function for research in HIV virology and immunovirology and that this function be placed with one of the laboratories or institutions that has received funding for the core research.
98. That there be no restrictions on National Centre in HIV Virology Research researchers applying for NHMRC or Australian Research Council funding as a result of receiving funding for core research or the networking function.
99. That the researchers currently involved in the National Centre in HIV Virology Research be encouraged to apply jointly for funding for the 'core research' and networking function.
100. That the researchers currently involved in the National Centre in HIV Virology Research be supported and encouraged to develop expertise in obtaining competitive funding to pursue innovative investigator-initiated research.
101. That the Population Health Division of the Department of Health and Ageing continue to fund the National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society for at least the next five years—initially, through a new five-year funding agreement.
102. That a new process for determining the research priorities of the National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society, drawing in other researchers and stakeholders, be developed.
103. That both the National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society be encouraged to nurture social research outside Sydney and Melbourne through collaborative projects and mentoring. This would include developing HIV social research expertise outside the two major Centres.
104. That both the National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society—and the former in particular—pursue their host universities for increased support, in recognition of the kudos they bring to their hosts.
105. That the processes of funding and administering the funding of the National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society remain with the Population Health Division of the Department of Health and Ageing. Should the Department choose to transfer this function to another body, however, the conditions specified in recommendations 101 to 104, and any others that may be identified by the advisory structure in consultation with the two Centres, should still be met.

106. That the Population Health Division of the Department of Health and Ageing continue to fund the National Centre in HIV Epidemiology and Clinical Research for at least the next five years—initially, through a new five-year funding agreement.
107. That the National Centre in HIV Epidemiology and Clinical Research pursue its host university for increased support, in recognition of the kudos it brings to its host.
108. That the National Centre in HIV Epidemiology and Clinical Research explore ways of expanding the reach of its expertise—particularly in communicable diseases surveillance and in conducting clinical trials in the primary care setting—into other areas of concern to the Population Health Division.
109. That the Population Health Division continue to provide the National Centre in HIV Epidemiology and Clinical Research with additional funds for hepatitis C surveillance and that these funds be rolled into the Centre's core funding.
110. That the processes of funding and administering the funding of the National Centre in HIV Epidemiology and Clinical Research remain with the Population Health Division. Should the Department choose to transfer this function to another body, however, the conditions specified in recommendations 106 to 109, and any others that may be identified by the advisory structure in consultation with the Centre, should still be met.
111. That strategic hepatitis C research be acknowledged as central to the Australian response to hepatitis C. Processes should be set up and resources allocated accordingly.
112. That the Population Health Division explore with the NHMRC and the Australian Research Council ways of funding a program of hepatitis C research over a long-term time frame, such as through Partnership funding.
113. That the Department of Health and Ageing explore ways in which research into the sexual health of Indigenous Australians, as well as hepatitis C and HIV in this population, can be supported and funded through appropriate mechanisms, integrating this with the current reform agenda in Aboriginal research that is being developed nationally.
114. That the Population Health Division resume dialogue with AusAID with a view to obtaining funding support for Australian researchers to work in HIV-related research in the Asia-Pacific region.
115. That the Population Health Division explore ways of accessing research expertise to assist with the management of a research program, including developing priorities for research and translating the research results into policy and practice.
116. That the Clinical Trials and Research Committee of ANCAHRD be abolished and a revised advisory structure be formed, with HIV/AIDS, hepatitis C and Indigenous sexual health committees having a mixture of policy and research expertise. The advisory structure's overarching body should have only minimal influence on the work of these committees.

117. That there be a triennial time frame for setting research priorities in the areas of HIV/AIDS, hepatitis C and the sexual health of Indigenous Australians. All the relevant stakeholders should be involved in deciding the priorities, and the process should include a review of research undertaken to that time.
118. That the research priorities determined for each three-year period be communicated to the NHMRC and the Australian Research Council, with a view to influencing funding decisions. The priorities should be used to assess the significance of competitive grant applications in the areas of HIV/AIDS, hepatitis C and Indigenous Australians' sexual health.
119. That, wherever possible, competitive funding sources be used for funding priority research and that core funding provided to the Centres be used for research that is of the highest priority and/or would be unlikely to be funded through competitive processes.
120. That the NHMRC, the advisory structure replacing the Clinical Trials and Research Committee, and the Population Health Division of the Department review the practice of restricting competitive grant applications by the Centres, with a view to removing the restrictions in the light of the processes recommended here.
121. That the role of the Centres' Scientific Advisory Committees be strengthened and broadened to include overseeing, monitoring and communication tasks. The name 'Scientific Advisory Committee' might need to be changed to reflect this.

4.2 THE REVIEW PROCESS

In order to support the 2002 reviews of the National HIV/AIDS Strategy 1999–2000 to 2003–04 and the National Hepatitis C Strategy 1999–2000 to 2003–04, a separate process for reviewing the status and future of Australia's research efforts in HIV/AIDS, hepatitis C and related diseases was established. The purpose of the Strategy Research Review was:

- ◆ having regard to the outcomes of the 2002 quinquennial review of the National Centres in HIV Research and submissions from key stakeholders, to assess the effectiveness of the current national research centre approach to supporting the objectives of the National HIV/AIDS Strategy, the National Hepatitis C Strategy and the Indigenous Australians' Sexual Health Strategy
- ◆ to develop recommendations on the most appropriate method or structure for supporting such research into the future.

Section 4.10 (Appendix A) shows the full Terms of Reference.

The members of the Strategy Research Review Team were:

- ◆ Dr Linda Selvey, Manager Communicable Diseases Unit, Queensland Health (Chair)
- ◆ Associate Professor Ian Anderson, Koori Health Research and Community Development Unit and Centre for the Study of Health and Society, University of Melbourne
- ◆ Professor John Mathews, Medical Director, Population Health Division, and Deputy Chief Medical Officer, Commonwealth Department of Health and Ageing
- ◆ Professor Sally Redman, NHMRC
- ◆ Dr Stuart Shapiro, Division of AIDS, US National Institutes of Health.

Secretariat support was provided by Paul Lehmann (Director) and Debra Gradie (Assistant Director), HIV/AIDS Section, Commonwealth Department of Health and Ageing.

Interested parties were invited to make submissions to the review. Sixteen submissions were received and considered by the Review Team. Written submissions specific to the Review Team's Terms of Reference were received from:

- ◆ the Australian Federation of AIDS Organisations
- ◆ the Australasian Society for HIV Medicine
- ◆ the Blood Borne Virus Consortium of Victoria
- ◆ the Victorian Department of Education, Employment and Training
- ◆ the Indigenous Australians' Sexual Health Committee of ANCAHRD
- ◆ the Office for Aboriginal and Torres Strait Islander Health, Commonwealth Department of Health and Ageing.

The Review Team also considered submissions presented to the various panels responsible for the quinquennial review of the National Centres in HIV Research.

The Review Team convened in Sydney from Monday 3 June to Friday 7 June 2002. It interviewed a range of stakeholders and other interested parties between 3 and 5 June. Section 4.11 (Appendix B) shows the program of interviews and details of the parties who attended.

4.3 BACKGROUND

[This section is based on material in the *Review of Australian HIV/AIDS Research* by Dr Lawrence Stedman (August 1999).]

Dedicated funding for HIV/AIDS research in Australia was introduced in the mid-1980s, although Australian researchers had been working on AIDS for some time before this, particularly in Sydney, where the epidemic first appeared. Initially, the Commonwealth's response to supporting such research was developed within the NHMRC framework: the NHMRC established the Working Party on AIDS in 1983; and in 1985 the AIDS Task Force used the NHMRC procedures to assess and support a number of applications for AIDS research, notably two cohort studies—the Social Aspects for the Prevention of AIDS Study and the Sydney AIDS Study Group. In 1986 two research centres were established, drawing together a number of existing project grants. The centres focused on virology research (the National Centre in HIV Virology Research, based at Fairfield Hospital in Melbourne) and epidemiology and clinical research (the National Centre in HIV Epidemiology and Clinical Research, based in Sydney).

In 1987 the research program was separated from the NHMRC upon establishment of the Commonwealth AIDS Research Grants Committee (CARG), which reported to the Australian National Council on AIDS. The CARG Committee initially modelled its processes on those of the NHMRC, including the design of grant application forms and the preparation of a 'case for funds', a mechanism replaced after 1989 by the funding of research through the framework of the National HIV/AIDS Strategies. During the 1989–1993 term of the first National HIV/AIDS Strategy significant increases in research funding were forthcoming.

The CARG Committee's immediate challenge was to develop ways of overseeing a research program that needed to be closely linked to the National HIV/AIDS Strategy. There were four main components to this challenge:

- ◆ developing priorities for research
- ◆ developing mechanisms for fostering research in strategic areas
- ◆ linking research with practice
- ◆ reflecting the partnership approach of the National HIV/AIDS Strategy in the research program.

Over time the Committee also modified the application forms and assessment procedures in an effort to accommodate the necessary diversity of research methods. Although initially the Committee had only one medical social scientist as a member, this later changed with the inclusion of researchers reflecting a broader range of disciplines.

The first National HIV/AIDS Strategy also saw the establishment of a third research centre, the National Centre in HIV Social Research, in 1990, as a network. The Centre was located at the University of Queensland, with two Sydney nodes involving social researchers who had also previously been active in this area.

The CARG Committee established three study groups to assess proposals for research: virology and immunology; clinical research and epidemiology; and social and behavioural

research. These groups examined applications and independent peer assessors' reports of those applications, and their recommendations were combined to make overall funding recommendations through the Australian National Council on AIDS to the Minister for Health.

The research program was evaluated in 1992 as part of a review of the first National HIV/AIDS Strategy. The evaluation report noted, 'Australian HIV/AIDS researchers have made significant contributions to the understanding of HIV/AIDS, both in Australia and internationally' and went on to recommend improved coordination and management of the three Centres and simplification of the objectives of the research program. It also foreshadowed a gradual transfer of responsibility for research management to the NHMRC. The recommendations were incorporated in the second National HIV/AIDS Strategy 1993–94 to 1995–96.

The second National HIV/AIDS Strategy built on emerging knowledge from both the national and the international perspectives, observing that the epidemic appeared to have stabilised and remained largely concentrated in particular population groups, most notably homosexually active men. In the Strategy the first indications were given of 'mainstreaming'—working to integrate HIV/AIDS approaches into more generic programs and services, particularly for communicable diseases and research.

In 1993 responsibility for the CARG Committee secretariat was transferred from the Department of Health to the NHMRC, and in 1994 the three HIV Research Centres moved to five-year funding with reviews scheduled in the fourth year, in keeping with procedures for block funding by the NHMRC. In 1995 responsibility for managing CARG project grants was also transferred to the NHMRC, which initially recorded CARG grant applications separately but in later years included them with other applications for NHMRC Project Grants. In 1996 the CARG Committee was reconstituted as the Research Advisory Committee of what was by now called the Australian National Council on AIDS and Related Diseases (ANCARD). While the NHMRC did the processing and ranking of applications and managed funded projects, the CARG secretariat returned to the Department of Health. Recommendations for funding were still made by ANCARD via the NHMRC to the Minister for Health, on the basis of the rankings provided by the NHMRC.

The HIV/AIDS research program was re-evaluated as part of the evaluation of the second National HIV/AIDS Strategy in 1995, which was undertaken by Professor Richard Feachem of the London School of Hygiene and Tropical Medicine. The evaluation drew on the outcomes of Australian research in the field and on a series of specifically commissioned studies in the areas of epidemiology, economic evaluation, and analysis over time of social and behavioural aspects among groups experiencing elevated levels of vulnerability to infection.

Professor Feachem's report, *Valuing the past ... investing in the future: evaluation of the National HIV/AIDS Strategy 1993–94 to 1995–96*, noted the many contributions made by the Australian HIV/AIDS research effort and the general satisfaction with the mechanisms then used for managing the research program. The report gave more detailed consideration to the question of the relationship between research and practice, noting that responsibilities for this were not clearly delineated. In addition, some concern about the national scope of the work of the Research Centres was expressed, particularly in relation to the epidemic as experienced outside south-eastern Australia. The report also cautioned against the wholesale mainstreaming of HIV/AIDS research into the NHMRC, on the grounds that dedicated

HIV/AIDS research funding was still warranted and that there were concerns about maintaining links between research and policy and a capacity to respond to urgent problems. It did, however, recommend that the research program be widened to encompass communicable diseases and that

From a public health perspective, there is also the question of the declining marginal benefits of researching HIV/AIDS. There is a continuing need to maintain a research effort that monitors the pattern of the epidemic in both epidemiological and social and behavioural terms, but there may be limits to which additional research can enhance the development of public health interventions.

The third National HIV/AIDS Strategy 1996–97 to 1998–99, called *Partnerships in Practice*, firmly placed future responses to HIV/AIDS within the broader context of communicable diseases and sexual health and established much stronger priorities for allocation of resources. The Strategy document stated,

The prime focus for minimising HIV transmission is gay and homosexually active men and Aboriginal and Torres Strait Islander people, but the Strategy is designed in such a way as to optimise the capacity to respond flexibly to any changes in the nature of the epidemic. Injecting drug users will continue to be identified as a high priority for education and prevention programs to control hepatitis C and to limit the possibilities of a future HIV epidemic among them.

The concept of research under the third Strategy was defined to encompass

... aspects of sexual health and communicable diseases that have an obvious and direct relationship to HIV/AIDS, which should be dealt with in a complementary and, where appropriate, integrated way in terms of policy frameworks, funding arrangements and service delivery structures, while maintaining the partnership approach.

The third Strategy further stated,

There is some overlap between HIV/AIDS and hepatitis C and other sexually transmitted diseases—in modes of transmission, affected populations, and similarities in community education approaches—and there is benefit to be gained from concurrent research. Links with existing research networks in the area of illicit drug use will be strengthened. Particular attention will be paid to ensure that this Strategy establishes strong links with the initiatives arising from the National Drug Strategy determinations. Although HIV/AIDS remains central to this Strategy, other important aspects of public health that are directly related to HIV/AIDS will be brought within the ambit of research activities.

Following the launch of the third Strategy, a new committee, the Research Advisory Committee of ANCARD, replaced the CARG Committee. The Research Advisory Committee was charged with a role that was intended to give greater emphasis to strategic considerations rather than grant management.

While supporting the continuation of dedicated funding for HIV/AIDS research, the third National HIV/AIDS Strategy clearly indicated that this was not envisaged as an ongoing arrangement: 'It should be noted ... that in the current environment of increased funding for health research the Commonwealth Government is disposed to progressively remove this type of funding arrangement, within a fixed time frame'.

In practice, the broadening of the research agenda beyond HIV/AIDS proved difficult to reflect in operational terms. The research program continued to focus almost exclusively on HIV/AIDS and only limited emphasis was given to hepatitis C-related research. The latter

was, however, the subject of a separate one-off allocation of funds, with \$1 million from the NHMRC's Strategic Research Development Committee's Social and Behavioural Research Program into Hepatitis C being allocated in the Committee's own budget in 1998.

The third National HIV/AIDS Strategy also anticipated that the broadening of the research program would extend the work of the Research Centres:

These Centres have been responsible for providing information and data relevant to policy objectives. In keeping with current policy, the Centres' research activities will include other communicable diseases, such as hepatitis C, where there is a clear and direct link to HIV/AIDS.

This was referred to in the 1997 review of the Centres, which noted and endorsed some expansion in the Centres' activity, particularly in relation to hepatitis C research.

The 1997 review of the National Centre in HIV Social Research recommended further changes to the management of the Centre. It was recommended, among other things, that the Centre

- ◆ be reconstituted as a single centre under one director, with the (then) Centre for the Study of Sexually Transmitted Diseases based at La Trobe University joined as a formal collaborating centre
- ◆ move from Macquarie University to the University of New South Wales.

Both recommendations were subsequently put into effect.

The National Centre in HIV Epidemiology and Clinical Research and the National Centre in HIV Virology Research were also reviewed in 1997, by panels whose membership included distinguished international researchers. As part of their review, the panels were asked to advise on the value of supporting the Centres, as opposed to grants or other mechanisms. While recommending various levels of change, the review panels emphasised—in some cases very strongly—the importance of maintaining the National Centres in HIV Research as a central element of the HIV/AIDS research program. Following the 1997 review, new five-year funding agreements were entered into with each of the Centres; these funding agreements conclude at the end of December 2003. A reconstituted Scientific Advisory Committee was also established for each Centre at this time.

In responding to the review panels' recommendations and subsequent advice from ANCARD, the Minister for Health and Family Services was, with one exception, in agreement with ANCARD's advice. The exception related to the National Centre in HIV Virology Research review panel's recommendation that existing funding arrangements for the Centre be maintained. The Minister preferred the view expressed in the Feachem report—that the Centre appeared to be well placed to be transferred to the NHMRC as part of the general move to mainstream research funding for HIV/AIDS.

In June 1998 the Minister requested that ANCARD and the NHMRC jointly review the current arrangements and develop a strategy to progress mainstreaming of research into HIV/AIDS and related diseases where this had been identified as the most appropriate course of action.

As a result, the joint ANCARD–NHMRC Working Party on HIV/AIDS Research Funding was formed and prepared a draft memorandum of understanding (MoU) in 1999. However,

delays associated with the establishment of both the new NHMRC and the new ANCAHRD meant that the MoU was not finalised until 2001, eventually being signed on 27 September. The MoU details the administrative and financial responsibilities of the signatories until 31 December 2003. Importantly, it describes the arrangements whereby access to competitive funds is granted to researchers from within the Research Centres. It also establishes arrangements and time frames for the transfer of responsibility and funding for other elements of the research program, as applicable, in preparation for 2004 and beyond.

In accordance with this direction, and independently of other developments, responsibility for funding and administration of individual CARG project grants and training awards was transferred to the NHMRC from the beginning of 2001. In relation to the National Centre in HIV Virology Research, the delay in finalising the September 2001 MoU and the need to give sufficient notice to the Centre's researchers to apply for NHMRC funding have resulted in limited progress toward mainstreaming that Centre.

The third National HIV/AIDS Strategy was reviewed in 1999 and the fourth National HIV/AIDS Strategy 1999–2000 to 2003–04, called *Changes and Challenges*, was released in 2000, alongside the first National Hepatitis C Strategy 1999–2000 to 2003–04. To advise the Commonwealth on implementation of these two Strategies, as well as the National Indigenous Australians' Sexual Health Strategy, a new ministerial advisory council, ANCAHRD, was established in late 1999.

The fourth National HIV/AIDS Strategy sets out the challenges, objectives and guiding principles for HIV/AIDS research. Although mainstreaming is not specifically discussed in the Strategy document, there is reference to the need to 'adapt successfully to the changes taking place in health and medical research as a result of the Health and Medical Research Strategic Review [the Wills review]'. The document also highlights the need for HIV/AIDS research priority setting to be informed by continuing review. Further—and for the first time in an Australian HIV/AIDS strategy—the development of vaccines for HIV is highlighted as an important area for research.

The first National Hepatitis C Strategy also highlights the importance of research in responding to the hepatitis C epidemic in Australia. The need to boost hepatitis C surveillance and monitoring efforts is noted in the Strategy document as a particular priority.

In relation to the research program, ANCAHRD's committee structure incorporated a new committee responsible for providing advice on research matters, the Clinical Trials and Research Committee. This committee assumed responsibility for functions that were previously the province of the former ANCARD's Research Advisory Committee and Clinical Trials and Treatments Advisory Committee. One of the Clinical Trials and Research Committee's principle roles has been to provide advice on the content of Research Centres' work plans, to ANCAHRD and ultimately to the Department of Health and Ageing.

The decision by the Minister for Health and Ageing in early 2002 to review the fourth National HIV/AIDS Strategy and the first National Hepatitis C Strategy, together with the scheduled quinquennial review of the National Centres in HIV Research, affords an excellent opportunity to take stock of Australia's research efforts in these areas. The purpose of this present review is to do this and to make recommendations for the way forward, having regard to historic developments, current arrangements, and what is needed for Australia's future response to HIV/AIDS, hepatitis C and related diseases and the sexual health of Indigenous Australians.

4.4 SCIENTIFIC QUALITY AND COMPETITIVENESS

4.4.1 The National Centre in HIV Virology Research

HIV research

The panel that reviewed the National Centre in HIV Virology Research found that the Centre is continuing to carry out internationally competitive research of the highest quality. The panel's report is provided as Chapter 5 of this document.

The panel noted that, in spite of the limitations imposed by geographical distance, there had been significant networking and communication between the different Centre sites, and this was an important factor in improving the quality of the science. The panel considered that the Centre's structure fosters this networking, which is difficult to foster in other circumstances.

The process of expanding the funding sources for research done by the Centre began five years ago in response to the recommendations of the 1997 quinquennial review. This process, combined with a series of difficulties culminating in the recent resignation of the Centre's Director, has caused some disruption to the work of the Centre. This is worth noting, particularly given that the Centre has continued to produce high-quality research.

The research done by the Centre has contributed to the understanding of the replication, pathogenesis and transmission of HIV, with a view to the development of vaccines and new treatment strategies. By this definition, the research has been strategic in nature, even though it has predominantly been investigator-initiated. There has been a tension between the desire and the need to do this innovative, creative work and the need for work that is less innovative and creative but that meets a strategic need. Examples of the latter are subtyping of viral isolates and drug-resistance studies of isolates from seroconverters. Such work is referred to here as *core research* (monitoring and strategic research). It is essential to understanding the epidemic in Australia and to developing vaccines and treatment strategies, but it is unlikely that it would be funded through the competitive funding streams. The review panel considered this work is best done by research laboratories of high standing, rather than service laboratories, to enable the recognition of, and rapid and innovative responses to, findings that are of particular interest. However, the Centre has not always done this work, despite being urged to do so by ANCAHRD.

The panel acknowledged that the emergence of such a tension is quite natural. Innovation is by its nature more interesting and satisfying, and innovative work is important for developing a competitive track record. In addition, it seems that there have been communication failures, to the extent that participating laboratories were not always made aware of the importance of doing this kind of research. It was agreed that this work should be a fundamental component of any future work of the Centre, in its current or a different incarnation. This may necessitate the involvement of expertise not available in the Centre at present—for example, expertise in immunovirology.

All HIV research, but especially HIV virology and immunology research, is best interpreted in the context of the body of knowledge in that area. This is essential if the work is to guide Australia's response to the epidemic. The review panel considered that the Centre's work in interpreting HIV virology and immunology research and influencing policy and strategic

directions has to date been insufficient and should be strengthened. This is discussed in more detail in Chapter 5 of this document.

For understandable reasons, the affected communities were in the past less involved in setting priorities in HIV virology and immunology research than in other areas of the HIV research response. More recently, however, their involvement has increased, as a result of the National Association of People Living with HIV/AIDS being represented on the Scientific Advisory Committee. Improving the capacity to interpret and contextualise the research will increase affected communities' involvement.

The review panel was satisfied that all the recommendations of the 1997 quinquennial review of the National Centre in HIV Virology Research have been met.

Recommendation 89

That the outgoing Director of the National Centre in HIV Virology Research be congratulated for the Centre's excellent work in carrying out important, internationally recognised research that is of very high quality and significance.

Recommendation 90

That the National Centre in HIV Virology Research, under the leadership of a Director, develop a strategic plan for the duration of its current funding cycle. This plan should guide the Centre's progress towards obtaining competitive funding; it should also include the important core research work (research that is highly strategic but may not necessarily be innovative). The strategic planning process should involve all stakeholders, including the HIV/AIDS advisory structure and the Department of Health and Ageing.

Hepatitis C research

To date, the National Centre in HIV Virology Research has not been involved in significant hepatitis C research. After the 1997 review, there was an attempt to include a team working on hepatitis C virology in the Centre, but this was not agreed to by the NHMRC, which was funding the team. The human immunodeficiency and hepatitis C viruses have in common the ability to evade the host's immune response and to form a number of different quasi-species in a single host. Areas of synergy provide opportunities for HIV virologists to expand their work and expertise into hepatitis C research. It is unrealistic, though, for this to be attempted in areas where the overlap does not exist.

Recommendation 91

That scientists in the National Centre in HIV Virology Research review areas of commonality between the hepatitis C and human immunodeficiency viruses and their immunovirology and strengthen links with virologists working on hepatitis C in Australia and elsewhere. Where appropriate, funding could be sought for this research through the competitive grant processes.

4.4.2 The National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society

HIV/AIDS research

The panel that reviewed the National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society found the work of the two Centres to be of consistently high quality and of international standing. The panel's report is provided as Chapter 6 of this document.

The panel noted that the Centres' research was highly relevant to and important for influencing the prevention and management of HIV infection in Australia. It found no areas of work done by the Centres using core funding that were not directly relevant to priorities set in the current National HIV/AIDS Strategy. Nor did it find any conflict between the work done by the two Centres; it considered that their work is complementary.

The review panel did not identify any specific concerns in relation to the Centres' implementation of the recommendations of the 1997 quinquennial review.

The review panel noted some priorities for HIV social research for Australia in the next five years. The Strategy Research Review Team considers that the priority-setting process for HIV social research needs improvement and recommends that the priorities identified in the 2002 quinquennial review report be used to assist with this.

The two Centres have been exemplary in involving the affected communities in priority setting for their research, as well as providing information about the outcomes of the research. The Directors and staff of both Centres are involved in several national advisory committees. The Strategy Research Review Team considers, however, that the Centres could improve their processes for informing the advisory structure and government of the content of the research, its significance for policy, and the importance of undertaking it.

The review panel was satisfied that all the recommendations of the 1997 quinquennial review of the National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society have been met.

Recommendation 92

That the National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society be congratulated for their high-quality, internationally recognised work in HIV social research.

Hepatitis C research

Both the National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society have done some hepatitis C research within their core funding and have done other hepatitis C research using other funding sources. The Strategy Research Review Team notes that, with no new allocation for hepatitis C research in the core funding, it will be difficult for the Centres to do significant work in this area without impinging on their HIV research.

The Review Team acknowledges the importance of developing close links with injecting drug users in order to do high-quality social research in this group, even though this is difficult to achieve. The Australian Research Centre in Sex, Health and Society is to be congratulated, however, for its success in this regard and for its commitment to involving the affected communities in work on hepatitis C and injecting drug use. The Review Team also acknowledges that other research centres, such as the National Centres on Drug Research—the National Drug Research Institute, the National Drug and Alcohol Research Centre, and the National Centre for Education and Training on Addiction—may have considerable expertise in this area, and it recommends stronger links between the National Centres on Drug Research, the National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society in carrying out hepatitis C social research. This is particularly important because of the lack of uniformity around Australia in relation to drug use patterns.

Recommendation 93

That—where it is possible, feasible and appropriate—the National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society engage with National Centres on Drug Research when doing work relating to injecting drug users.

4.4.3 The National Centre in HIV Epidemiology and Clinical Research

HIV/AIDS research

The review panel for the 2002 quinquennial review of the National Centre in HIV Epidemiology and Clinical Research found that the Centre's research is of outstandingly high quality and is internationally recognised. The panel's report is provided as Chapter 7 of this document.

The panel did not find fault with the quality or volume of work done by the Centre in all its areas of activity. In its report the panel listed several important achievements it wanted to highlight, among them the Centre's outstanding publication record: in the last five years the Centre has published 295 peer-reviewed articles, at least 130 of them appearing in journals with an impact factor of five or greater.

With the exception of four recommendations, as detailed in the 2002 quinquennial review report, the review panel was satisfied with the action taken to respond to the recommendations of the 1997 quinquennial review. Both the review panel and the Strategy Research Review Team consider that the recommendations that have not been implemented in full are either in the process of being implemented or require additional assistance to be implemented.

The Centre uses several mechanisms to engage with affected communities, among them the communities' representation on the Scientific Advisory Committee and working groups. All the submissions from the affected groups praised the Centre for its work and for involving them in it.

The Centre's work influences policy and strategy formulation in a number of ways. It publishes an excellent annual surveillance report that summarises the epidemiology of HIV,

hepatitis C and STIs in Australia. The Director and staff of the Centre are involved in a number of national committees and working groups. And, through the clinical trials network, the Centre supports clinical practice and has fostered a unique environment in which its primary care practitioner treats the majority of people living with HIV.

Recommendation 94

That the Director and Deputy Director of the National Centre in HIV Epidemiology and Clinical Research be congratulated for their outstanding achievements in HIV epidemiology, surveillance and clinical research.

Hepatitis C research

With the assistance of a small amount of additional funding, the National Centre in HIV Epidemiology and Clinical Research has been able to incorporate hepatitis C surveillance in its work plan. The recent establishment of the Viral Hepatitis Working Group, in cooperation with the Australian Liver Association, will allow the Centre to expand its expertise in clinical trials to assessment of treatments for both hepatitis B and C. This will greatly augment the Centre's contribution to hepatitis C research, as well as expanding both national and international capacity in this area.

4.5 FUNDING ARRANGEMENTS

4.5.1 The National Centre for HIV Virology Research

The provision of block funding to the National Centre in HIV Virology Research has been essential for generating a critical mass in HIV virology research in Australia. Funding of this kind has also been very useful in improving networking and cooperation between the various laboratories, thus promoting an interdisciplinary research response. This has resulted in Australia being an international leader in HIV virology.

Previous reviews recommended that the funding and administration of the Centre be transferred to the NHMRC and that in future the Centre's funds be largely obtained through the competitive funding process. This was not fully implemented, and the Population Health Division still funds and administers the Centre. However, as a result of the 2001 MoU between the NHMRC, ANCAHRD and the Population Health Division, all the National Centres in HIV Research have been able to apply for competitive grant funding for research in areas that do not overlap with those covered by core funding. As a result, laboratories within the National Centre in HIV Virology Research have obtained some competitive funding.

The review panel concluded that continuing to provide block funding for the Centre beyond December 2004 is not appropriate. It reached this conclusion for the following reasons:

- ◆ An internationally competitive critical mass of HIV virologists has now been established in Australia, so the primary purpose of establishing the Centre has been achieved.
- ◆ It is inappropriate for the Population Health Division to directly fund basic science research in one field of its endeavours to the exclusion of others if this research is not performing a monitoring or strategic function.
- ◆ With the exception of the non-innovative but strategic research referred to elsewhere, the style of research undertaken by the Centre—that is, investigator-initiated, innovative research—should be amenable to funding by the NHMRC and other sources.
- ◆ Block funding may be limiting the amount of funding available for HIV virological research, by virtue of inhibiting the success of competitive grant funding applications. For example, the Centre's researchers may not be developing the skills required to successfully apply for competitive funding (as evidenced by an unsuccessful NHMRC Program Grant application in 2002). The Centre's researchers may also not be gaining access to the breadth of funding potentially available to them because of a lack of incentive to do so.

The review panel did, however, consider it essential for the 'core research' (monitoring and strategic research)—which is unlikely to be funded through the competitive funding process but is important for the response to HIV—to be funded directly. In its view, this work is best done by leading researchers in HIV virology and immunovirology (many of whom currently form part of the Centre) but some of the necessary expertise may exist outside the Centre. The process for developing the list of core research to be purchased is described in Section 4.9 of this chapter.

The panel also considered it would be necessary to provide funding for a networking function. This function would enable and improve communication between virologists working in the field of HIV and related viruses and promote interdisciplinary research, both within Australia and with other countries. The function could include activities such as fostering an annual meeting or workshop, circulation of newsletters, and other relevant activities.

It is expected that the funds required for these two functions (core research and networking) would amount to about half the funds currently provided to the Centre—that is, about \$1.0–1.5 million—although this will need to be more accurately costed after the priorities for the core research have been defined.

The Strategy Research Review Team considers that these two functions do not constitute a National Centre, but rather a ‘national network’. It also considers that the necessary funding should be allocated through a competitive process and that the networking function should be supported in one of the laboratories or institutions where some of the core research functions have already been purchased. Among the selection criteria for funding both the core research and the networking functions might be interest and expertise in communication of research findings, significance and objectives; an ability to network with other scientists in Australia and elsewhere; an ability to link the core research activities with innovative research; and responsiveness to the needs and priorities identified by the Department of Health and Ageing together with its advisory structure.

The Review Team does not consider it part of its brief to make recommendations about the process for allocating this competitive funding. The Population Health Division may not have the expertise needed to evaluate the scientific merit of the applications, although it may be well placed to evaluate in terms of the other selection criteria. A process involving the NHMRC, the Population Health Division and the advisory structure may therefore be the most suitable. However, the advantage of the Population Health Division maintaining a funding role is that this would streamline communications between the Department and members of the national network, as well as increase the ‘leverage’ of the Department in ensuring the network’s responsiveness.

The only research that would be funded through this process is core research, so it should then be possible for researchers funded to do this work to have unrestricted access to competitive funding processes. The Population Health Division and ANCAHRD should begin discussions with the NHMRC as soon as possible to ensure that these restrictions on accessing competitive funding processes are lifted.

The Strategy Research Review Team wants to make it very clear that the recommendation to discontinue funding for the National Centre in HIV Virology Research does not reflect a lack of confidence in the Centre’s research quality or the capabilities of the researchers involved. On the contrary, it could be argued that this recommendation is made on the basis of the success of the Centre’s research and the fact that its international competitiveness means that obtaining competitive funding should not be difficult. The researchers may not be accustomed to applying for NHMRC and other competitive funding, and they should be supported in doing so. The following are examples of how this could be done:

- ◆ If the decision is made to terminate the block funding of the Centre at the end of December 2004 (or sooner), this should be communicated to the Centre as rapidly and as clearly as possible.

- ◆ The Centre's researchers should be encouraged to make joint funding bids for core research activities and for the networking function.
- ◆ In order to hone their skills in applying for funding from NHMRC Program Grants, the Centre's researchers could 'team up' with researchers who have been successful in obtaining such funding.
- ◆ Details of other funding sources, such as US National Institutes of Health grants, could be obtained from the relevant sources.

Recommendation 95

That block funding for the National Centre in HIV Virology Research cease at the end of December 2004.

Recommendation 96

That a process be developed and funds be identified for purchasing 'core research' in HIV virology and immunovirology.

Recommendation 97

That a process be developed and funds be identified for purchasing a networking and communication function for research in HIV virology and immunovirology and that this function be placed with one of the laboratories or institutions that has received funding for the core research.

Recommendation 98

That there be no restrictions on National Centre in HIV Virology Research researchers applying for NHMRC or Australian Research Council funding as a result of receiving funding for core research or the networking function.

Recommendation 99

That the researchers currently involved in the National Centre in HIV Virology Research be encouraged to apply jointly for funding for the 'core research' and networking function.

Recommendation 100

That the researchers currently involved in the National Centre in HIV Virology Research be supported and encouraged to develop expertise in obtaining competitive funding to pursue innovative investigator-initiated research.

4.5.2 The National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society

Both the National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society have produced internationally recognised, high-quality social research. Importantly, this has been possible partly because of the development of close relationships with affected communities and regular liaison with these groups. In turn, these close relationships have allowed a transfer of knowledge that has led to the development of successful prevention strategies. Although this has, to a degree, impeded the Centres' ability to publish in the peer-reviewed literature, the Centres have still managed to develop a significant portfolio of publications in the peer-reviewed literature. The Strategy Research Review Team considers that these relationships and the liaison process are basic functions of the two Centres and that they make a significant contribution to the infrastructure that is necessary to support social research in this area.

The review panel considered that the current funding arrangements for both Centres have resulted in excellent value for money. This is a result of the quality of the research that has been done, the engagement with affected communities, the dissemination of the research results, and the ability of both Centres to attract considerable outside funding to supplement their research. The review panel also considered that the work done under the block funding arrangements has met some of the strategic needs of the National HIV/AIDS Strategy and, to a lesser extent, the National Hepatitis C Strategy. In its view, the work would largely be considered core research, defined as monitoring or strategic research that would be unlikely to be funded through competitive funding processes. The panel also considered that the community liaison functions undertaken by both Centres represent an essential activity but one that would be unlikely to obtain funding from elsewhere.

Submissions to the review almost uniformly supported these conclusions. Some stakeholders, however—particularly those from outside Sydney and Melbourne—considered that the Centre's current research does not meet their needs. It was also recognised that the smaller states and territories do not have the funds to purchase research that would meet local needs where these might differ from those associated with the main focus of the epidemic, in Sydney and Melbourne. The review panel considered that these were problems that should not be overlooked. It noted that the work of both Centres would benefit from more strategic planning and that this planning should involve all the relevant stakeholders. The Strategy Research Review Team outlines a process for this planning in Section 4.9.

The review panel was also concerned that the expertise in HIV social research is currently focused in Sydney and Melbourne. The disadvantage of this is that it may limit the Centres' ability to respond to changes in the epidemic or to other matters, such as hepatitis C and STIs. This is because the Centres may not have had the opportunity to build relationships with affected communities elsewhere. The review panel noted that the expertise needed for high-quality social research in the area of HIV and STIs might not exist outside the two Centres.

The Strategy Research Review Team would therefore encourage both Centres to foster the development of expertise in other parts of Australia, through collaborative projects and mentoring.

Both Centres have strong links with their host universities. This is an essential component of their sustainability, particularly as they grow. It would appear that the support from the host university for the Australian Research Centre in Sex, Health and Society is stronger than that from the host university for the National Centre in HIV Social Research: the former has been provided with tenure for its senior researchers and is likely to soon receive support for 50 per cent of the Director's salary. The Review Team acknowledges, however, that the University of New South Wales (the host institution for the National Centre in HIV Social Research) has recently made a commitment to increase its support for the Centre and strongly supports this.

The Review Team therefore considers that the Population Health Division should continue to fund both Centres to current funding levels for at least the next five years. It also considers, however, that a new process should be developed to set the research priorities and that a more open process should be developed for seeking competitive funding for other priority research. (These processes are outlined in Section 4.9.) The Review Team also examined the question of whether the Population Health Division should continue to fund the Centres directly or whether funding should be provided through a body such as the NHMRC or the Australian Research Council. While acknowledging that this is a matter for the Department, the Team cannot see any advantage in transferring this responsibility to another body. If the Department does decide to transfer funding responsibility to another body, however, the Team considers that the following conditions should be maintained:

- ◆ an ability for the advisory structure and the Department to directly discuss with the Centres their work plans as related to the funding
- ◆ an ability for the advisory structure and the Department to set the research priorities for the Centres
- ◆ an ability for the Centres to provide to the advisory structure, the Department and other stakeholders feedback on the results and significance of their work
- ◆ minimal disruption to the work of the Centres
- ◆ an assurance that any assessment process for the Centres would involve the expertise necessary for evaluating social research.

It was the review panel's view that the funding for the two Centres should continue only so long as HIV is a priority for the Department. Should there be changes in the nature of the epidemic as a result of successful vaccine development or a cure, the Department might decide that HIV is no longer a priority. Nevertheless, the panel did not see this as likely to happen within the next decade.

Recommendation 101

That the Population Health Division of the Department of Health and Ageing continue to fund the National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society for at least the next five years—initially, through a new five-year funding agreement.

Recommendation 102

That a new process for determining the research priorities of the National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society, drawing in other researchers and stakeholders, be developed.

Recommendation 103

That both the National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society be encouraged to nurture social research outside Sydney and Melbourne through collaborative projects and mentoring. This would include developing HIV social research expertise outside the two major Centres.

Recommendation 104

That both the National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society—and the former in particular—pursue their host universities for increased support, in recognition of the kudos they bring to their hosts.

Recommendation 105

That the processes of funding and administering the funding of the National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society remain with the Population Health Division of the Department of Health and Ageing. Should the Department choose to transfer this function to another body, however, the conditions specified in recommendations 101 to 104, and any others that may be identified by the advisory structure in consultation with the two Centres, should still be met.

4.5.3 The National Centre in HIV Epidemiology and Clinical Research

The Strategy Research Review Team considers that the current funding arrangement for the National Centre in HIV Epidemiology and Clinical Research is efficient, cost-effective and appropriate. The Centre has been able to expand its research income many times over by attracting funding from other sources, including overseas; this has facilitated the Centre's expansion to 70 staff, with significant research output. The overseas research funding includes a significant National Institutes of Health grant for a vaccine initiative; this funding is being shared between a number of research bodies in Australia (including the National Centre in HIV Social Research and the National Centre in HIV Virology Research), with the goal of developing and trialling an HIV vaccine. The funding provided to the Centre through the block funding arrangements is used almost exclusively for core research—monitoring or strategic research that would be unlikely to attract funding from other sources but that is a priority for the National HIV/AIDS Strategy. The funding is also used to provide infrastructure to enable the research to be done; examples of this are the clinical trials network and the Australian HIV Observational Database. The Centre's strong international

standing and its history of engaging with clinicians, researchers and epidemiologists, throughout the country and internationally, are further evidence that the current funding arrangement is suitable and cost-effective.

Within its Terms of Reference and current priorities, the Centre is meeting the research needs of its disciplines. The review panel recommended, however, that the Centre make use of or obtain expertise in anti-retroviral pharmacology, to extend the reach of its clinical research. The Centre should be encouraged to do this. The Centre's ability to acquire expertise in a number of areas that are central to its work is a good example of how providing support for core research through block funding can enable the acquisition of funding for other priority research through competitive sources.

Both the review panel and the Strategy Research Review Team consider that the Centre should be better supported by its host institution, the University of New South Wales, especially since the Centre is a flagship for the University. The University has indicated a willingness to review its level of support, with view to increasing that support in the future. This is important for the Centre's sustainability.

The Review Team notes the opportunities for the Centre to expand its role in a number of related areas. It is already extending its surveillance capacity to hepatitis C and STIs, and it would be worthwhile exploring with the Communicable Diseases Network Australia ways in which Australia's surveillance capacity in other communicable diseases might be expanded with the Network's support. The Centre is already involved in aspects of Creutzfeldt–Jakob disease surveillance and, with its future involvement in clinical trials involving hepatitis B and C, it is expanding its reach in this area. There may, however, be opportunities to also extend its expertise in clinical trials in the primary care setting to other conditions of public health importance, possibly through providing training and support for other groups to do similar work in other areas.

The Centre currently receives a small amount of additional funding for hepatitis C surveillance. The Review Team recommends that this funding be continued and that it be rolled into the Centre's core funding.

The Review Team therefore recommends that the Centre continue to be funded through a block funding arrangement for at least five years. The funding should not be expected to continue indefinitely; it would be expected to cease when HIV is no longer a priority for the Department. Such a scenario could be expected to arise if an effective vaccine or cure, or both, were developed, but this does not seem imminent.

The Review Team considers that the current funding arrangement for the Centre—through the Population Health Division—is the best way of administering the funds. This is because the funds are being used to support core public health activity and because the current arrangement appears to be working well. If the Department decides to transfer the funding process to another body, however, the Review Team considers that the following conditions should be maintained:

- ◆ an ability for the advisory structure and the Department to directly discuss with the Centre its work plan as related to the funding
- ◆ an ability for the advisory structure and the Department to set the research priorities for the Centre

- ◆ an ability for the Centre to provide to the advisory structure, the Department and other stakeholders feedback on the results and significance of its work
- ◆ minimal disruption to the work of the Centre.

Recommendation 106

That the Population Health Division of the Department of Health and Ageing continue to fund the National Centre in HIV Epidemiology and Clinical Research for at least the next five years—initially, through a new five-year funding agreement.

Recommendation 107

That the National Centre in HIV Epidemiology and Clinical Research pursue its host university for increased support, in recognition of the kudos it brings to its host.

Recommendation 108

That the National Centre in HIV Epidemiology and Clinical Research explore ways of expanding the reach of its expertise—particularly in communicable diseases surveillance and in conducting clinical trials in the primary care setting—into other areas of concern to the Population Health Division.

Recommendation 109

That the Population Health Division continue to provide the National Centre in HIV Epidemiology and Clinical Research with additional funds for hepatitis C surveillance and that these funds be rolled into the Centre's core funding.

Recommendation 110

That the processes of funding and administering the funding of the National Centre in HIV Epidemiology and Clinical Research remain with the Population Health Division. Should the Department choose to transfer this function to another body, however, the conditions specified in recommendations 106 to 109, and any others that may be identified by the advisory structure in consultation with the Centre, should still be met.

4.6 HEPATITIS C RESEARCH

All stakeholders, including the Population Health Division, recognise that incorporation of hepatitis C research in the core HIV research agenda has not been successful in meeting the strategic research needs of hepatitis C, with the exception of a few small areas. Although there are areas of overlap between HIV and hepatitis C research, there are important areas where the research agendas do not overlap. Further, even carrying out research in overlapping areas can require additional resources, but very few extra resources have been provided for hepatitis C research in Australia.

The formation of the Australian Viral Hepatitis C Centre is an important initiative in developing hepatitis C viral research. While it is not currently supported by block funding, additional support will increase the Centre's capacity to pursue important hepatitis C virological research.

Australia's experience in managing HIV demonstrates the importance of research as the basis for a successful response. This is reflected in both the National HIV/AIDS Strategy and the National Hepatitis C Strategy.

The Review Team also points out that, as with HIV research, engagement of the affected communities in determining research directions and communicating research results is essential to the success of the research endeavour.

As noted, funding of \$1 million for the NHMRC's Strategic Research Development Committee's Social and Behavioural Research Program into Hepatitis C was allocated from the Committee's own budget in 1998. The funded projects have yielded useful results, but their short-term nature meant that it was not possible for strategic engagement of researchers with the issues pertaining to hepatitis C. This is not mentioned as a criticism of the Strategic Research Development Committee; rather, it is to point out that a sustained research response requires sustained funding. The Review Team considers that, in order to be successful in meeting public health needs, hepatitis C research should focus on specific priority areas and should build up over time.

The Review Team explored ways in which hepatitis C research could be encouraged in Australia. At present the Australian Research Council and the NHMRC each have a new funding model that offers significant funding for a program of research over a five-year period. Partners contribute funding to the research effort and participate in defining the research agenda. In both of the models—called *Discovery funding* by the Australian Research Council and *Partnership funding* by the NHMRC—each organisation can contribute funds. Since funding for hepatitis C research comes within the remit of both the NHMRC and the Australian Research Council, there is potential to develop a partnership between the NHMRC, the Australian Research Council, the Population Health Division and other stakeholders in funding hepatitis C research. This could also provide a very good model for funding other areas of population health. The partnership, which can involve others who do not necessarily contribute funds to research (for example, the community sector), is also responsible for setting the strategic direction of the research program and monitoring its outcomes.

The NHMRC and the Australian Research Council also provide funding for new researchers, to encourage them to take up research in particular areas. This is another potential source of funding for hepatitis C research that should be explored further.

Recommendation 111

That strategic hepatitis C research be acknowledged as central to the Australian response to hepatitis C. Processes should be set up and resources allocated accordingly.

Recommendation 112

That the Population Health Division explore with the NHMRC and the Australian Research Council ways of funding a program of hepatitis C research over a long-term time frame, such as through Partnership funding.

4.7 RESEARCH INTO INDIGENOUS AUSTRALIANS' SEXUAL HEALTH

As in other areas of public health, research has been integral to the development of strategies for responding to concerns in relation to the sexual health of Indigenous Australians, as well as hepatitis C in this population. Although both the Australian Research Centre in Sex, Health and Society and the National Centre in HIV Epidemiology and Clinical Research have been involved in research or surveillance of importance to Indigenous Australians' sexual health, the subject has not been a strong research focus for any of the Centres. The Mapping Indigenous Risk project funded by the Department of Health and Ageing was an important initiative in which key research questions were identified. In order to develop a strong research response, however, it is necessary to develop a critical mass of research expertise in Indigenous sexual health and in hepatitis C.

The Review Team considers that the NHMRC funding model for research through the competitive grant processes has not been successful in engendering the research response required in this area. This is possibly because a number of the research questions are not 'innovative', because sometimes research questions in Indigenous sexual health need to be defined by the communities involved, and because some of the other criteria for assessing research grant applications may not be suited to evaluating research in Indigenous sexual health and hepatitis C. This may also be a problem for research in other areas relating to Indigenous health. In addition, other important initiatives in the area of Indigenous health research have been introduced in order to respond to these and other issues. The Review Team considers, however, that opportunities to build a critical mass of expertise in research into Indigenous Australians' sexual health should be explored. The new funding models developed by the NHMRC and the Australian Research Council—involving a partnership approach, as described in Section 4.6—may also be relevant here.

Recommendation 113

That the Department of Health and Ageing explore ways in which research into the sexual health of Indigenous Australians, as well as hepatitis C and HIV in this population, can be supported and funded through appropriate mechanisms, taking the lead from the current reform agenda in Aboriginal research that is being developed nationally.

4.8 INTERNATIONAL HIV RESEARCH

The 1997 quinquennial reviews of both the National Centre in HIV Social Research and the National Centre in HIV Epidemiology and Clinical Research recommended that the Centres extend their area of research internationally, particularly in the Asia–Pacific region, which is of critical importance to Australia. This recommendation is consistent with the fourth National HIV/AIDS Strategy. Both Centres, as well as the Australian Research Centre in Sex, Health and Society, have carried out some research in the Asia–Pacific region, and it is recognised that the vaccine initiative (see Chapter 7) will require additional social and epidemiological research in order to prepare for a phase III vaccine trial. However, the difficulty of obtaining funding constitutes an important barrier to doing HIV research in the region. This means that the expertise developed in the Centres has not been used to benefit the region to the fullest extent.

The 1997 review of the National Centre in HIV Epidemiology and Clinical Research recommended that the Department develop a dialogue with AusAID in order to explore mechanisms whereby AusAID might support the work of the Centres in the Asia–Pacific region. To date, however, this has not resulted in an appropriate funding stream. Recent restructuring within AusAID might open doors for further discussions of this matter, so the Review Team recommends that such a dialogue be resumed.

The Review Team also considers that there are opportunities for the National Centre in HIV Social Research and the Australian Research Centre in Sex, Health and Society to make significant contributions to HIV social research in the region. Researchers not involved in the National Centres also have contributions to make.

The NHMRC's recent announcement of collaboration with the Wellcome Trust to fund the work of Australian researchers overseas also provides an opportunity to extend the reach of Australian HIV researchers into the Asia–Pacific region.

Recommendation 114

That the Population Health Division resume dialogue with AusAID with a view to obtaining funding support for Australian researchers to work in HIV-related research in the Asia–Pacific region.

4.9 FUTURE SYSTEMS FOR SUPPORTING STRATEGY RESEARCH IN HIV/AIDS, HEPATITIS C AND RELATED DISEASES

The Strategy Research Review Team agrees that, although Australia's research effort in HIV/AIDS has been exemplary, there is a need to strengthen the links between the research effort and policy and implementation. Stakeholders should be more involved in setting the research agenda. There also needs to be a much stronger process for reviewing the research results and assessing their implications for policy and practice. Several important gaps in the current research effort were identified during the review.

The Review Team is also aware that there is important research done in Australia that is relevant to the National HIV/AIDS Strategy and the National Hepatitis C Strategy but that falls outside of the Centres. This research is even less likely to be influenced by national priorities or to influence policy and practice, since there is at present no satisfactory mechanism for doing so. Finally, important research is being done internationally but its significance may not be reflected in the policy agenda.

These problems were recognised on a broader level in the 1999 Health and Medical Research Strategic Review report, *The Virtuous Cycle—working together for health and medical research*, known as the Wills report. Although the NHMRC should be commended for its efforts to date, it has not made sufficient progress in dealing with these problems. The Review Team also considers that the Population Health Division has some role in developing or harnessing the expertise to gain access to and interpret research information relevant to its area of responsibility. This might involve developing within the Division a critical mass of expertise that is capable of interpreting research in the different disciplines relevant to public health in Australia, including HIV/AIDS. Another possibility would be to obtain this expertise within the advisory structure for HIV/AIDS and related diseases, although this would have the disadvantage of being small and therefore not being able to sustain an active and able workforce.

Many of the stakeholders who contributed to this review were of the opinion that the current advisory structure creates a division between the research and policy areas that is not conducive to the development of stronger links between policy and research. Specifically, some stakeholders recommended that the Clinical Trials and Research Committee of ANCAHRD be disbanded and that its research expertise be incorporated in the HIV, Hepatitis C and Indigenous Sexual Health Sub-committees. Some stakeholders also expressed the view that the current overarching body, ANCAHRD, provides a confusing structure, where some of the important views of the Sub-committees are lost. The Review Team agrees. It therefore recommends a revised advisory structure, in which there are three committees—HIV/AIDS, Hepatitis C and Indigenous Sexual Health—that each contain expertise in policy and research as well as the relevant community sector. The person chairing each committee should have expertise in either policy or research and the deputy chair should have expertise in the other area. The overarching body would then consist only of the chairs and deputy chairs of the three committees, with or without an independent chair. Its role should be to act largely as a conduit for communication between the three committees, as well as being a convenient mechanism for communication between the advisory structure and outside agencies.

The Review Team considers that the advisory structure should play a central part in setting the research agenda but that it should not be responsible for this alone. Rather, the Team recommends a triennial process for setting research priorities for the next three years. This process should involve all key stakeholders, including the advisory structure and researchers themselves, and could take the form of a workshop (or series of workshops) that would, among other things, review the research that has been done in the preceding three years. The outcome should be a list of research priorities, in order of importance, for each area of work (that is, HIV/AIDS, hepatitis C and Indigenous sexual health) and each discipline (that is, social research and epidemiology). This list of research priorities should be widely distributed, with a view to influencing the work done by researchers seeking funding through the competitive grant process as well as the Centres. The list of priorities should also be presented to the NHMRC and the Australian Research Council and be used by grant assessors to assess the significance of research grant applications in the areas of HIV/AIDS, hepatitis C and Indigenous sexual health.

The Centres should develop a three-year strategic plan in response to these research priorities; the plan should detail the research to be funded through the Centre's core funding as well as through other sources. They should also be encouraged to use the list of research priorities to collaborate with other groups and apply for competitive research funding to meet the priorities. Where possible, the Centres should seek competitive funding to meet the research priorities, their core funding being used to fund areas of research that are of the highest priority and/or are unlikely to be funded through competitive processes. Each year the Centres would then provide the Population Health Division (or their funder) with a costed work plan relating to their core funding. The plan would be forwarded to the advisory structure for information and to provide an overview of the full research agenda undertaken by the Centres. This would ensure that there is no overlap between the work of the different Centres and no significant gaps in research activity.

If this procedure were followed, the Review Team considers it would obviate the need to review all NHMRC grant applications by the Centres for overlap with their core-funded research, as happens at present. The current process does not represent an efficient use of resources and also may inhibit the Centres' creativity as a result of micro-management and confusion about procedure. As with its recommendation for basic virology research, therefore, the Review Team recommends that the Population Health Division, the advisory structure and the NHMRC review the funding processes with a view to eliminating the need to restrict competitive funding of research undertaken by the Centres.

The Review Team also considers that the role of the Centres' Scientific Advisory Committees should be strengthened. These Committees would have a key role in developing the work plans of the Centres, and the Population Health Division would have input into the work plans largely through membership of the Committees. Further, the Scientific Advisory Committees should play a central role in monitoring the Centres' progress against the work plans and assessing and communicating the implications of the research. The Scientific Advisory Committees would be mandated to cover the core funded research, but there would be strategic value in them looking at this research in the context of the Centres' broader research programs. This broader role goes beyond that of a 'Scientific Advisory Committee', and the Review Team therefore recommends that the Committees be renamed—for example, Scientific and Strategic Steering Committee—to reflect this broader role.

Recommendation 115

That the Population Health Division explore ways of accessing research expertise to assist with the management of a research program, including developing priorities for research and translating the research results into policy and practice.

Recommendation 116

That the Clinical Trials and Research Committee of ANCAHRD be abolished and a revised advisory structure be formed, with HIV/AIDS, hepatitis C and Indigenous sexual health committees having a mixture of policy and research expertise. The advisory structure's overarching body should have only minimal influence on the work of these committees.

Recommendation 117

That there be a triennial time frame for setting research priorities in the areas of HIV/AIDS, hepatitis C and the sexual health of Indigenous Australians. All the relevant stakeholders should be involved in deciding the priorities, and the process should include a review of research undertaken to that time.

Recommendation 118

That the research priorities determined for each three-year period be communicated to the NHMRC and the Australian Research Council, with a view to influencing funding decisions. The priorities should be used to assess the significance of competitive grant applications in the areas of HIV/AIDS, hepatitis C and Indigenous Australians' sexual health.

Recommendation 119

That, wherever possible, competitive funding sources be used for funding priority research and that core funding provided to the Centres be used for research that is of the highest priority and/or would be unlikely to be funded through competitive processes.

Recommendation 120

That the NHMRC, the advisory structure replacing the Clinical Trials and Research Committee, and the Population Health Division of the Department review the practice of restricting competitive grant applications by the Centres, with a view to removing the restrictions in the light of the processes recommended here.

Recommendation 121

That the role of the Centres' Scientific Advisory Committees be strengthened and broadened to include overseeing, monitoring and communication tasks. The name 'Scientific Advisory Committee' might need to be changed to reflect this.

4.10 APPENDIX A TERMS OF REFERENCE

The following Terms of Reference were issued for the 2002 review of the National Centres in HIV Research, the Strategy Research Review and the discipline-specific review panels.

A.1 The 2002 Review of the National and Collaborating Centres in HIV Research

Preamble

This review will focus on assessing the scientific quality and international competitiveness of the research effort conducted at the Centres in HIV Research under the National HIV/AIDS Strategy 1999–2000 to 2003–04, *Changes and Challenge*; the National Indigenous Australians' Sexual Health Strategy 1996–97 to 1998–99; and the National Hepatitis C Strategy 1999–2000 to 2003–04. This review is conducted within the context of Australia's system of funding health and medical research (including the application of research to public health and health care). The overall purpose of the review is to ascertain the effectiveness of the current Centres in supporting research required to deliver Strategy objectives and to develop recommendations about the best method or structure for supporting strategy research.

The reviews of the National HIV/AIDS and Hepatitis C Strategies

The proximity of the timing of the quinquennial review with the reviews of the current National HIV/AIDS and Hepatitis C Strategies (due to commence in 2002/2003), will provide the opportunity the former to be an adjunct to the latter. In this way the recommendations arising from the quinquennial review will not only inform the future of HIV/AIDS and hepatitis C research arrangements but will also inform the respective National Strategy reviews.

Hepatitis C research

It is acknowledged that the Centres were established and funded under the National HIV Strategies. With regard to hepatitis C research, the current Hepatitis C Strategy was launched in June 2000 without specific funding for implementation and the hepatitis C activities of Centres have arisen out of specific negotiations with the Department of Health and Ageing.

Mainstreaming and the 2001 Administrative Review of National Centre in HIV Virology Research

The former Federal Health Minister, the Hon Dr Michael Wooldridge, stated that strategy research will continue to be funded through the Population Health Division until the end of 2003, but non-strategy research is to be 'mainstreamed'—that is, to compete for funding through the NHMRC grants system. A MoU between the Population Health Division, ANCAHRD and the NHMRC to establish arrangements and relevant time frames to allow a smooth transfer of responsibilities and research funding to 2003 has now been signed.

In 2001 an administrative review of the National Centre in HIV Virology Research was undertaken in the context of facilitating a successful 'transfer of funding of the National Centre in HIV Virology Research to the NHMRC'. This review was undertaken by a committee chaired by Dr Janice Hirshorn, with the final report being submitted to the Clinical

Trials and Research Committee and the Department of Health and Ageing on 20 August 2001. The final report of this review will inform the 2002 quinquennial review and will very likely result in a reduced submission being required from the National Centre in HIV Virology Research.

A.2 The Strategy Research Review Team

In the context of assessing the scientific quality and international competitiveness of research, the Strategy Research Review Team will review and make recommendations on:

Scientific quality and competitiveness

1. the performance of each Centre in meeting its objectives as defined under the guiding principles and priorities of the current National HIV/AIDS, National Hepatitis C and National Indigenous Australians' Sexual Health Strategies, and in terms of the quality and international competitiveness of its research effort.
2. the progress on the recommendations from the 1997 review of the Centres in HIV Research.

Funding arrangements

3. the appropriateness, efficiency and cost effectiveness of funding the Centres under the existing 5 year Commonwealth AIDS Research Grant (CARG) arrangements;
4. future responsibilities and operational requirements of the Centres including
 - possible changes to their role and function, both individually and as a group
 - the value of funding the Centres to produce quality research outcomes in line with established research priorities (ie those established by the National HIV/AIDS and Hepatitis C Strategies and ANCAHRD) as compared with alternative funding mechanisms, such as a competitive grants program (including the NHMRC grants program) and/or alternative research bodies
 - the manner in which the current Centres that were established and funded as HIV Centres have contributed, and can contribute in the future to, hepatitis C research;
5. future systems for supporting strategy research in HIV, hepatitis C and related diseases, including
 - systems for defining strategy research
 - systems for funding strategy research—that is, competitive application, contracting and/or commissioning
 - systems for monitoring strategy research to achieve objectives of quality and relevance
 - systems through which strategy advisory bodies (such as ANCAHRD), the NHMRC, the Australian Research Council and other Australian government research funding agencies can interact to discuss specific research priorities and programs.

4.11 APPENDIX B THE 2002 STRATEGY RESEARCH REVIEW: PROGRAM OF STAKEHOLDER INTERVIEWS

Time	Stakeholder	Representative
Monday 3 June		
1430–1500	Department of Health and Ageing	Greg Sam (Assistant Secretary, Communicable Diseases & Health Protection Branch)
Tuesday 4 June		
0930–1030	Australian Research Council	Douglas McEachern (Executive Director, Social Sciences)
1100–1130	Assoc. Prof. Nick Crofts, Burnet Institute (by phone)	
1130–1200	University of New South Wales	James Walsh (Director, Research Office) Prof. David Cooper (Director, NCHECR) Prof. John Kaldor (Deputy Director, NCHECR) Prof. Sue Kippax (Director, NCHSR) Bronwen Turner (Manager, Finance & Administration, NCHECR)
1200–1330	Melbourne University	John Gorry (Departmental Manager) Prof. Roy Robbins-Browne.
1330–1400	Australian Liver Association	Prof. Geoff McCaughan (Director, AW Morrow Gastroenterology & Liver Institute Centre, Royal Prince Alfred Hospital)
1400–1430	Australasian Society for HIV Medicine	Levinia Crooks (Executive Officer) Assoc. Prof. Andrew Grulich (President)
1430–1500	Australian Hepatitis Council Australian Injecting and Illicit Drug Users League	Jack Wallace (Executive Officer) Tamara Speed (President)
1630–1700	ANCAHRD	Chris Puplick (Chair, ANCAHRD).
Wednesday 5 June		
1330–1400	National Centre in HIV Virology Research	Prof. Tony Cunningham (Deputy Director)
1400–1430	National Centre in HIV Epidemiology and Clinical Research	Prof. David Cooper (Director) Prof. John Kaldor (Deputy Director) Bronwen Turner (Manager, Finance & Administration)

1430–1500	National Centre in HIV Social Research	Prof. Sue Kippax (Director) Dr Paul Van de Ven (Deputy Director)
1500–1530	Australian Research Centre in Sex, Health and Society	Prof. Marian Pitts (Director) Assoc. Prof. Gary Dowsett (Deputy Director)
1600–1700	Australian Federation of AIDS Organisations (AFAO); National Association of People Living With HIV/AIDS (NAPWA)	Don Baxter (Executive Director, AFAO) Phillip Medcalf (President, NAPWA) Peter Canavan (National Treatments Portfolio Convenor, NAPWA)
1700–1800	ANCAHRD	Dennis Altman (Deputy Chair, HIV Committee) Prof. Robert Batey (Chair, Hepatitis C Committee) Prof. Cindy Shannon (Chair, Indigenous Australians' Sexual Health Committee) Prof. Peter McDonald (Chair, Clinical Trials and Research Committee) Apology: Chris Puplick (Chair, ANCAHRD Executive)
